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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,540	02/26/2004	Urs Jorimann	032498-023	3251
21839	7590	09/12/2005		
BUCHANAN INGERSOLL PC (INCLUDING BURNS, DOANE, SWECKER & MATHIS) POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404			EXAMINER SHERR, CRISTINA O	
			ART UNIT 3621	PAPER NUMBER

DATE MAILED: 09/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/786,540

Applicant(s)

JORIMANN ET AL.

Examiner

Cristina Owen Sherr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2004.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-19 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 02/26/04.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This communication is in response to the application filed February 26, 2004.

Claims 1-19 have been examined in this case.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on February 26, 2004 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Specification

3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erickson (US 5,765,152).
6. Regarding claim 1 –

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Erickson discloses a method for controlling electronic records produced by an application software program, wherein the program and apparatus are used by designated users performing assigned user roles, said method comprising:

- (a) restricting access to the application software program to the designated users through a user authentication; (e.g. col 4 ln 55 – col 5 ln 5)
- (b) assigning a set of user rights to each user role, wherein said designated users are divided into a first group of users who are given a right to sign the electronic records and a second group who are denied the right to sign the electronic records; (e.g. col 4 ln 55-60)
- (c) storing the electronic records in a protected data file format; (e.g. col 5 ln 1-10)
- (d) maintaining a history of access entries and activities performed in the application software program; (e.g. col 5 ln 10-20) and
- (e) authenticating the electronic records by means of at least one electronic signature by one of the users of the first group, wherein access to step (e) of the method is denied to users of the second group. (e.g. col 4 ln 55 – ln 5 ln 55).

7. Although Erickson does not specifically refer to records produced for an analytical software program, it would be obvious to one of ordinary skill in the art to adapt the teachings of Erickson, for any type of copy righted material or any type of material to which one wishes to limit access for any reason.

8. Regarding claims 2-3 –

Erickson the method of claim 1, wherein access to step (e) is subject to an additional user authentication.

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9. As above, Erickson does not disclose the method of claim 1, wherein the method conforms to a set of requirements issued by the U.S. Federal Food and Drug Administration (FDA) and known as "Title 21, CFR Part 11 - Electronic Records; Electronic Signatures", nevertheless it would be obvious to one of ordinary skill in the art to adapt the teachings of Erickson, for any type of copy righted material or any type of material to which one wishes to limit access for any reason.

10. Regarding claims 4-10 –

Erickson discloses the method of claim 1, wherein the at least one electronic signature comprises a plurality of electronic signatures, wherein a signature meaning is attached to each of said plurality of electronic signatures, said signature meaning being selected from a list of signature meanings, wherein the signature meaning indicates a signature status that an electronic record will have as a result of an electronic signature, and wherein each signature meaning in said list is correlated with a signature level in a hierarchy ascending from a lowest to a highest signature level, so that each of said plurality of electronic signatures is hierarchically ranked by way of its attached meaning; wherein the hierarchically ranked meanings include at least one of the meanings "Tested", "Reviewed", "Approved", and "Released"; wherein each user of the first group is assigned a maximum signature level that is selected from the signature levels in said list, and wherein said user is not allowed to attach to his/her signature a signature meaning that exceeds said user's assigned maximum signature level; wherein said maximum signature level is assigned to a user in accordance with the user role performed by said user; wherein when the electronic record has already been signed at

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least once, said user is not allowed to attach to his/her signature a signature meaning that ranks lower than the signature status which the electronic record has as a result of said at least one previous signature; wherein when the electronic record has already been signed at least once, said user is not allowed to attach to his/her signature a signature meaning that does not rank at least one level higher than the signature status which the electronic record has as a result of said at least one previous signature; wherein said user is only allowed to attach to his/her signature a signature meaning exactly one level higher than the signature status which the electronic record has as a result of said at least one previous signature, so that said plurality of signatures follow each other in consecutive ascending order of signature level (e.g. col 7 ln 20-60).

11. As above, although Erickson does not use the same terminology as the instant case, it would be obvious to one of ordinary skill in the art to change terminology or reorder step as needed in order to adapt Erickson to any sort of data requiring several levels of access.

12. Regarding claims 11-12 –

Erickson discloses the method of claim 4, wherein a record is fully authenticated after a prescribed number of signatures comprising at least two different signature levels have been attached to said record; wherein the at least two different signature levels comprise a prescribed hierarchically ascending series of signature levels (e.g. col 7 ln 20-60).

13. Regarding claims 13 –

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Erickson discloses the method of claim 1, wherein step (e) comprises attaching a remark to the electronic signature (e.g. col 6 ln 20-35).

14. Regarding claims 14 – 15 –

Erickson discloses the method of claim 4, wherein the signature levels attached to the signature meanings in said list from the lowest to the highest level are consecutive ascending numbers starting at the number one; wherein the signature levels attached to the signature meanings in said list from the lowest to the highest level are nonconsecutive ascending numbers, leaving unused numbers available for additional intermediate signature levels (e.g. col 6 ln 20-35).

15. Regarding claims 16-17 –

Erickson discloses the method of claim 6, wherein parts (a) and (b) of the method are performed by a system administrator; wherein said parts (a) and (b) include at least one of: assigning user names and passwords to the designated users, retiring said user names and passwords, assigning the maximum signature level to each user account, and defining the signature meanings and ranking them according to signature levels (e.g. col 6 ln 20-35).

16. Regarding claim 18 –

Erickson discloses an application software program that implements a method for controlling electronic records, wherein the method comprises a signing procedure for authenticating the electronic records with a plurality of electronic signatures, with the following steps:

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- (a) designating a first group of users who are given a right to sign the electronic records and a second group of users who are denied the right to sign the electronic records; (e.g. col 4 ln 55 – col 5 ln 5)
- (b) restricting access to the signing procedure to the users of the first group through a verification routine in said application software program; (e.g. col 4 ln 55-60)
- (c) establishing a list of signature meanings to be attached to the electronic signatures, wherein each signature meaning in said list is ranked according to a signature level defined as an ordinal number; (e.g. col 5 ln 1-10)
- (d) assigning to each user of the first group a maximum signature level; (e.g. col 5 ln 10-20) and
- (e) controlling said signing procedure so that the user can sign a record only with a signature meaning that ranks not lower than any previous signature attached to the record and not higher than the user's maximum signature level. (e.g. col 4 ln 55 – ln 5 ln 55).

17. Although Erickson does not specifically refer to records produced for an analytical software program, it would be obvious to one of ordinary skill in the art to adapt the teachings of Erickson, for any type of copy righted material or any type of material to which one wishes to limit access for any reason.

18. Regarding claim 19 –

Erickson discloses the application software program of claim 18, wherein step (e) comprises controlling said signing procedure so that the user can sign a record only

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with a signature meaning that ranks higher than any previous signature attached to the record, but not higher than the user's maximum signature level (e.g. col 5 ln 20-45).

19. Examiner's note: Examiner has cited particular columns and line numbers in the references as applied to the claims above for the convenience of the applicant.

Although the specified citations are representative of the teachings in the art and are applied to the specific limitations within the individual claim, other passages and figures may be applied as well. It is respectfully requested from the applicant, in preparing the responses, to fully consider the references in entirety as potentially teaching all or part of the claimed invention as well as the context of the passage as taught by the prior art or disclosed by the examiner.

Conclusion

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cristina Owen Sherr whose telephone number is 571-272-6711. The examiner can normally be reached on 8:30-5:00 Monday through Friday.

21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Trammell can be reached on 571-272-6712. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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22. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Olivia Anne J.
PRIMARY PATENT EXAMINER